

Serial No. 09/752,731

First Named Inventor: Lawrence Loomis

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cont, one lytic enzyme which is not selected from the group consisting of at least one shuffled lytic enzyme, chimeric lytic enzyme, and holin lytic enzyme.

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#### REMARKS

In response to the Office Actions question relating to the term "synergistically enhanced," applicants note that this phrase was used on page 17, lines 15-16.

The Office Action has rejected the above composition claim on the basis of obviousness-type double patenting. The Office Action cites to the following applications and patents:

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Rejected Claims	Patent or Patent Application	Claim Nos.	Claim
31-34	09/932,460	Claims 1-10	A method for treating dermatological bacterial infections
1-4, 6, 7	09/866,106	Claims 1, 4-6, 11, 12, 14, 15-17 and 20	A composition for treatment of bacterial infections, having a parenteral carrier
1-27, 31-56	09/908,737	Claims 26, 28, 31-41	A composition for treatment of a bacterial infection having a parenteral carrier
31, 33, 36-46	10/083,142	Claims 19, 20, 22-33	Lozenge for treating Hemophilus influenza
31, 33, 36-59	Pat. 6,423,299	Claims 1-9	An aerosol composition for treating bacterial infections of the respiratory tract
31, 33, 36-44, 56-59	Pat. 5,997,862	Claims 1, 3-11, and 13-15	A pharmaceutical composition for use in and 56-59 the treatment of a streptococcal infection, Claim 2 refers to Lozenges
31, 32, 34 and	Pat. 6,277,399	Claims 1, and 3-5	A composition for treating bacteria infecting burns and wounds of the skin, comprising: (a) an effective amount of at least one phage associated lytic enzyme (b) a topical carrier

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1-3, 15, 16, and 28-30	Pat. 6,238,661	Claims 1, 4-6, 11, 12, 14, 34, 36, 37, 50, and 51	Method for treating bacterial diseases. No mention made of parenteral uses
1-14, 17-25, 27, and 30	Pat.6,264,945	Claims 1-23	Parenteral use (method)
1-5, 26-30	Pat. 6,056,954	Claims 1, 4-10, 16, 17, 20	Method claims for treating Bacterial infections of skin, eyes, Vagina
31, 32, and 34	Pat 6,406,692	Claim 1	An eye drop solution for treating infections of the eye
31, 33, and 36-46	Pat. 6,017,528	Claims 1 and 3-16	A composition for use in the therapeutic or prophylactic treatment of a Group A streptococcal infection, comprising: an effective amount of lysin enzyme produced by Group C streptococcal bacteria infected with a CI bacteriophage; and a carrier for delivering said lysin enzyme to a mouth, throat, or nasal passage of a mammal.

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31 and 33	Pat. 6,399,098	Claim 1	A lozenge for treating bacterial dental caries caused by Streptococcus mutans, wherein said lozenge is produced by the method of: (a) obtaining at least one lytic enzyme, said at least one lytic enzyme being genetically coded for by a bacteriophage specific for said Streptococcus mutans, whereby said lytic enzyme has the ability to specifically digest a cell wall of said Streptococcus mutans, thereby causing lysis,
31	Pat. 6,399,097	1	An enteric coated pill for treating bacterial infections of the digestive tract, wherein the bacteria to be treated is selected from the group consisting of <i>Listeria</i> , <i>Salmonella</i> , <i>E. coli</i> , <i>Campylobacter</i> and combinations thereof
31-34 and 43	Pat. 6,432,444	Claim 1 -3	A composition for treating dermatological infections

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1	Pat. 6,254,866	Claim 1	A method for the treatment of bacterial infections of the digestive tract, comprising administering orally or rectally to the digestive tract a composition comprising an effective amount of at least one lytic enzyme produced by a bacteriophage
1, 3, 6-16	6,326,002	1-14	A method for the treatment of the upper respiratory tract.
1,3, and 6-16	Pat. 5,985,271	1-16	Treating Strep infections oral administration
1, 3, 6-9, 14, 15, and 20	Pat. 6,248,324	1, 5-8, 10-12	Treating topical dermatological infections
1, 3, 6-16, 20, 31, 33, 38-46, 50 and 56-69	Pat. 6,056,955	Claim 1,2, 5-13, 15-22, and 25-40	A composition for the treatment of dermatological streptococcal infections

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The present invention is for a product-by-process for a parenteral therapeutic agent containing lytic enzyme to treat a bacterial disease, which is specific for a specific bacteria. Of the cited patents and applications, however, none claim parenteral compositions. Indeed, only one patent, U.S. 6,264,945, contains the word parenteral in the claims, but the '945 patent claims methods of treatment, not compositions. The cited patents and applications are discussed below:

Claims 1-10 of U.S. Patent No. 6,423,299 teaches or claims an aerosol composition for treating bacterial infections of the respiratory tract. There is no suggestion in the claims for a parenteral therapeutic agent.

U.S. Patent Nos. 6,277,399, 6,432,444 and 6,056,955 are for topical compositions for treating the skin. There are no claims suggesting a parenteral therapeutic agent.

Claim 1 of U.S. Patent No. 6,406,692 claims an eye drop solution for treating infections of the eye. There is no teaching or mention in the claim for a parenteral composition.

U.S. Patent No. 6,399,097 claims an enteric coated pill for treating bacterial infections of the digestive tract.

U.S. Patent No. 5,985,271 has claims for treating strep infections orally, and U.S. Patent No. 6,248,324 is directed towards treating topical dermatological infections.

Patent Application 10/083,142 and U.S. Patent No. 6,399,098 claims lozenges for treating upper respiratory ailments, and U.S. Patent No. 6,017,528 claims oral delivery of an enzyme composition.

U.S. Patent No. 6,238,661 discloses a method for treating bacterial diseases, but does not

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claim parenteral solutions.

U.S. Patent No. 6,264,945 claims methods of treating bacterial infections using parenteral enzyme compositions, not the compositions themselves as is claimed here.

Application Serial Nos. 09/908,737 and 09/866,106 have been amended and now claim syrup and chewing gum compositions, respectively. As such they also are not relevant to the pending claimed parenteral compositions.

In sum, none of the cited patents and applications claim parenteral compositions, including parenteral carriers. The Examiner is thus respectfully requested to reconsider and withdraw all obviousness-type double patenting rejections and pass this case to issue. Applicants note the Examiner's request in paragraph 27 and shortly will file an Information Disclosure Statement. The Examiner is respectfully requested to call the undersigned at (301) 603-9071 if there are any questions or comments.

Respectfully submitted,



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